II

107TH CONGRESS
1ST SESSION

# S. 925

To amend title XVIII of the Social Security Act to provide a prescription benefit program for all medicare beneficiaries.

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IN THE SENATE OF THE UNITED STATES

MAY 22, 2001

Mr. WELLSTONE introduced the following bill; which was read twice and referred to the Committee on Finance

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# A BILL

To amend title XVIII of the Social Security Act to provide a prescription benefit program for all medicare beneficiaries.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

(a) SHORT TITLE.—This Act may be cited as the ''Medicare Extension of Drugs to Seniors (MEDS) Act of 2001''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

**SEC. 2. FINDINGS.**

Congress makes the following findings:

(1) Prescription medicine coverage was not a standard part of health insurance when the medicare program under title XVIII of the Social Security Act was enacted in 1965. Since 1965, however, medicine coverage has become a key component of most private and public health insurance coverage, except for the medicare program.

(2) At least ⅔ of medicare beneficiaries have unreliable, inadequate, or no medicine coverage at all.

(3) Seniors who do not have medicine coverage typically pay, at a minimum, 15 percent more than people with coverage.

(4) Medicare beneficiaries at all income levels lack prescription medicine coverage, with more than ½ of such beneficiaries having incomes greater than 150 percent of the poverty line.

(5) The number of private firms offering retiree health coverage is declining.

(6) Medigap premiums for medicines are too expensive for most beneficiaries and are highest for older senior citizens, who need prescription medicine coverage the most and typically have the lowest incomes.

(7) All medicare beneficiaries should have access to a voluntary, reliable, affordable, and defined outpatient medicine benefit as part of the medicare program that assists with the high cost of prescription medicines and protects them against excessive out-of-pocket costs.

**SEC. 3. PRESCRIPTION MEDICINE BENEFIT PROGRAM.**

(a) IN GENERAL.—Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended—

(1) by redesignating part D as part E; and

(2) by inserting after part C the following new part:

''PART D—PRESCRIPTION MEDICINE BENEFIT FOR THE AGED AND DISABLED

''ESTABLISHMENT OF PRESCRIPTION MEDICINE BENEFIT PROGRAM FOR THE AGED AND DISABLED

''SEC. 1860. There is established a voluntary insurance program to provide prescription medicine benefits, including pharmacy services, in accordance with the provisions of this part for individuals who are aged or disabled or have end-stage renal disease and who elect to enroll under such program, to be financed from premium payments by enrollees together with contributions from funds appropriated by the Federal Government.

''SCOPE OF BENEFITS

''SEC. 1860A. (a) IN GENERAL.—The benefits provided to an individual enrolled in the insurance program under this part shall consist of—

''(1) payments made, in accordance with the provisions of this part, for covered prescription medicines (as specified in subsection (b)) dispensed by any pharmacy participating in the program under this part (and, in circumstances designated by the Secretary, by a nonparticipating pharmacy), including any specifically named medicine prescribed for the individual by a qualified health care professional

regardless of whether the medicine is included in any formulary established under this part if such medicine is certified as medically necessary by such health care professional (except that the Secretary shall encourage to the maximum extent possible the substitution and use of lower-cost generics), up to the benefit limits specified in section 1860B; and

''(2) charging by pharmacies of the negotiated price—

''(A) for all covered prescription medicines, without regard to such benefit limit; and

''(B) established with respect to any drugs or classes of drugs described in subparagraphs (A), (B), (D), (E), or (F) of section 1927(d)(2) that are available to individuals receiving benefits under this title.

''(b) COVERED PRESCRIPTION MEDICINES.—

''(1) IN GENERAL.—Covered prescription medicines, for purposes of this part, include all prescription medicines (as defined in section 1860K(1)), including smoking cessation agents, except as otherwise provided in this subsection.

''(2) EXCLUSIONS FROM COVERAGE.—Covered prescription medicines shall not include drugs or classes of drugs described in subparagraphs (A)

through (D) and (F) through (H) of section 1927(d)(2) unless—

"(A) specifically provided otherwise by the Secretary with respect to a drug in any of such classes; or

"(B) a drug in any of such classes is certified to be medically necessary by a health care professional.

"(3) EXCLUSION OF PRESCRIPTION MEDICINES TO THE EXTENT COVERED UNDER PART A OR B.—A medicine prescribed for an individual that would otherwise be a covered prescription medicine under this part shall not be so considered to the extent that payment for such medicine is available under part A or B, including all injectable drugs and biologicals for which payment was made or should have been made by a carrier under section 1861(s)(2) (A) or (B) as of the date of enactment of the Medicare Extension of Drugs to Seniors (MEDS) Act of 2001. Medicines otherwise covered under part A or B shall be covered under this part to the extent that benefits under part A or B are exhausted.

"(4) STUDY ON INCLUSION OF HOME INFUSION THERAPY SERVICES.—Not later than 1 year after

the date of enactment of the Medicare Extension of Drugs to Seniors (MEDS) Act of 2001, the Secretary shall submit to Congress a legislative proposal for the delivery of home infusion therapy services under this title and for a system of payment for such a benefit that coordinates items and services furnished under part B and under this part.

''PAYMENT OF BENEFITS; BENEFIT LIMITS

''SEC. 1860B. (a) PAYMENT OF BENEFITS.—

''(1) IN GENERAL.—There shall be paid from the Prescription Medicine Insurance Account within the Supplementary Medical Insurance Trust Fund, in the case of each individual who is enrolled in the insurance program under this part and who purchases covered prescription medicines in a calendar year—

''(A) with respect to costs incurred for covered prescription medicine furnished during a year, before the individual has incurred out-of-pocket expenses under this subsection equal to the catastrophic out-of-pocket limit specified in subsection (b), an amount equal to the applicable percentage (specified in paragraph (2)) of the negotiated price for each such covered prescription medicine or such higher percentage as is proposed under section 1860G(b)(7); and

''(B) with respect to costs incurred for covered prescription medicine furnished during a year, after the individual has incurred out-of-pocket expenses under this subsection equal to the catastrophic out-of-pocket limit specified in subsection (b), an amount equal to 100 percent of the negotiated price for each such covered prescription medicine.

''(2) APPLICABLE PERCENTAGE.—The applicable percentage specified in this paragraph is 80 percent or such higher percentage as is proposed under section 1860G(b)(7), if the Secretary finds that such higher percentage will not increase aggregate costs to the Prescription Medicine Insurance Account.

''(b) CATASTROPHIC LIMIT ON OUT-OF-POCKET EXPENSES.—

''(1) IN GENERAL.—The catastrophic limit on out-of-pocket expenses specified in this subsection for—

''(A) for each of calendar years 2003 and 2004, $2,000; and

''(B) subject to paragraph (2), for calendar year 2005 and each subsequent calendar year is equal to the limit for the preceding year under this paragraph adjusted by the sustainable

growth rate percentage (determined under section 1861I(b)) for the year involved.

''(2) ROUNDING.—Any amount determined under paragraph (1)(E) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

''ELIGIBILITY AND ENROLLMENT

''SEC. 1860C. (a) ELIGIBILITY.—Every individual who, in or after 2003, is entitled to hospital insurance benefits under part A or enrolled in the medical insurance program under part B is eligible to enroll, in accordance with the provisions of this section, in the insurance program under this part, during an enrollment period prescribed in or under this section, in such manner and form as may be prescribed by regulations.

''(b) ENROLLMENT.—

''(1) IN GENERAL.—Each individual who satisfies subsection (a) shall be enrolled (or eligible to enroll) in the program under this part in accordance with the provisions of section 1837, as if that section applied to this part, except as otherwise explicitly provided in this part.

''(2) SINGLE ENROLLMENT PERIOD.—Except as provided in section 1837(i) (as such section applies to this part), 1860E, or 1860H(e), or as otherwise explicitly provided, no individual shall be entitled to enroll in the program under this part at any time

after the initial enrollment period without penalty, and in the case of all other late enrollments, the Secretary shall develop a late enrollment penalty for the individual that fully recovers the additional actuarial risk involved providing coverage for the individual.

''(3) SPECIAL ENROLLMENT PERIOD FOR 2003.—

''(A) IN GENERAL.—An individual who first satisfies subsection (a) in 2003 may, at any time on or before December 31, 2003—

''(i) enroll in the program under this part; and

''(ii) enroll or reenroll in such program after having previously declined or terminated enrollment in such program.

''(B) EFFECTIVE DATE OF COVERAGE.—An individual who enrolls under the program under this part pursuant to subparagraph (A) shall be entitled to benefits under this part beginning on the first day of the month following the month in which such enrollment occurs.

''(c) PERIOD OF COVERAGE.—

''(1) IN GENERAL.—Except as otherwise provided in this part, an individual's coverage under the program under this part shall be effective for the pe-

riod provided in section 1838, as if that section applied to the program under this part.

''(2) PART D COVERAGE TERMINATED BY TERMINATION OF COVERAGE UNDER PARTS A AND B.—In addition to the causes of termination specified in section 1838, an individual's coverage under this part shall be terminated when the individual retains coverage under neither the program under part A nor the program under part B, effective on the effective date of termination of coverage under part A or (if later) under part B.

''PREMIUMS

''SEC. 1860D. (a) ANNUAL ESTABLISHMENT OF MONTHLY PREMIUM RATES.—

''(1) IN GENERAL.—The Secretary shall, during September of 2002 and of each succeeding year, determine and promulgate a monthly premium rate for the succeeding year in accordance with the provisions of this subsection.

''(2) INITIAL PREMIUMS.—For months in 2003, the monthly premium rate under this subsection shall be—

''(A) $24, in the case of premiums paid by an individual enrolled in the program under this part; and

"(B) $32, in the case of premiums paid for such an individual by a former employer (as defined in section 1860H(f)(2)).

"(3) SUBSEQUENT YEARS.—

"(A) IN GENERAL.—For months in a year after 2003, the monthly premium under this subsection shall be (subject to subparagraph (B)) the monthly premium (computed under this subsection without regard to subparagraph (B)) for the previous year increased by the annual percentage increase in average per capita aggregate expenditures for covered outpatient medicines in the United States for medicare beneficiaries, as estimated and published by the Secretary in September before the year and for the year involved.

"(B) ROUNDING.—The monthly premium determined under subparagraph (A) shall be rounded to the nearest multiple of 10 cents if it is not a multiple of 10 cents.

"(C) PUBLICATION OF ASSUMPTIONS.—The Secretary shall publish, together with the promulgation of the monthly premium rates under this paragraph, a statement setting forth the actuarial assumptions and bases employed

in arriving at the monthly premium under subparagraph (A).

''(b) PAYMENT OF PREMIUMS.—

''(1) PAYMENTS BY DEDUCTION FROM SOCIAL SECURITY, RAILROAD RETIREMENT BENEFITS, OR BENEFITS ADMINISTERED BY OPM.—

''(A) DEDUCTION FROM BENEFITS.—In the case of an individual who is entitled to or receiving benefits as described in subsection (a), (b), or (d) of section 1840, premiums payable under this part shall be collected by deduction from such benefits at the same time and in the same manner as premiums payable under part B are collected pursuant to section 1840.

''(B) TRANSFERS TO PRESCRIPTION MEDICINE INSURANCE ACCOUNT.—The Secretary of the Treasury shall, from time to time, but not less often than quarterly, transfer premiums collected pursuant to subparagraph (A) to the Prescription Medicine Insurance Account from the appropriate funds and accounts described in subsections (a)(2), (b)(2), and (d)(2) of section 1840, on the basis of the certifications described in such subsections. The amounts of such transfers shall be appropriately adjusted

to the extent that prior transfers were too great or too small.

''(2) DIRECT PAYMENTS TO SECRETARY.—

''(A) ADDITIONAL PAYMENT BY ENROLLEE.—An individual to whom paragraph (1) applies (other than an individual receiving benefits as described in section 1840(d)) and who estimates that the amount that will be available for deduction under such paragraph for any premium payment period will be less than the amount of the monthly premiums for such period may (under regulations) pay to the Secretary the estimated balance, or such greater portion of the monthly premium as the individual chooses.

''(B) PAYMENTS BY OTHER ENROLLEES.—An individual enrolled in the insurance program under this part with respect to whom none of the preceding provisions of this subsection applies (or to whom section 1840(c) applies) shall pay premiums to the Secretary at such times and in such manner as the Secretary shall by regulations prescribe.

''(C) DEPOSIT OF PREMIUMS.—Amounts paid to the Secretary under this paragraph

shall be deposited in the Treasury to the credit of the Prescription Medicine Insurance Account in the Supplementary Medical Insurance Trust Fund.

''(c) CERTAIN LOW-INCOME INDIVIDUALS.—For rules concerning premiums for certain low-income individuals, see section 1860E.

''SPECIAL ELIGIBILITY, ENROLLMENT, AND COPAYMENT RULES FOR LOW-INCOME INDIVIDUALS

''SEC. 1860E. (a) STATE AGREEMENTS FOR COVERAGE.—

''(1) IN GENERAL.—The Secretary shall, at the request of a State, enter into an agreement with the State under which all individuals described in paragraph (2) are enrolled in the program under this part, without regard to whether any such individual has previously declined the opportunity to enroll in such program.

''(2) ELIGIBILITY GROUPS.—The individuals described in this paragraph, for purposes of paragraph (1), are individuals who satisfy section 1860C(a) and who are—

''(A)(i) eligible individuals within the meaning of section 1843; and

"(ii) in a coverage group or groups permitted under section 1843 (as selected by the State and specified in the agreement); or

"(B) qualified medicare medicine beneficiaries (as defined in subsection (e)(1)).

"(3) COVERAGE PERIOD.—The period of coverage under this part of an individual enrolled under an agreement under this subsection shall be as follows:

"(A) INDIVIDUALS ELIGIBLE (AT STATE OPTION) FOR PART B BUY-IN.—In the case of an individual described in subsection (a)(2)(A), the coverage period shall be the same period that applies (or would apply) pursuant to section 1843(d).

"(B) QUALIFIED MEDICARE MEDICINE BENEFICIARIES.—In the case of an individual described in subsection (a)(2)(B)—

"(i) the coverage period shall begin on the latest of—

"(I) January 1, 2003;

"(II) the first day of the third month following the month in which the State agreement is entered into; or

"(III) the first day of the first month following the month in which the individual satisfies section 1860C(a); and

"(ii) the coverage period shall end on the last day of the month in which the individual is determined by the State to have become ineligible for medicare medicine cost-sharing.

"(4) ALTERNATIVE ENROLLMENT METHODS.—In the process of enrolling low-income individuals under this part, the Secretary shall use the system provided under section 154 of the Social Security Act Amendments of 1994 for newly eligible medicare beneficiaries and shall apply a similar system for other medicare beneficiaries. Such system shall use existing Federal Government databases to identify eligibility. Such system shall not require that beneficiaries apply for, or enroll through, State medicaid systems in order to obtain low-income assistance described in this section.

"(b) SPECIAL PART D ENROLLMENT OPPORTUNITY FOR INDIVIDUALS LOSING MEDICAID ELIGIBILITY.—In the case of an individual who—

"(1) satisfies section 1860C(a); and

''(2) loses eligibility for benefits under the State plan under title XIX after having been enrolled under such plan or having been determined eligible for such benefits;

the Secretary shall provide an opportunity for enrollment under the program under this part during the period that begins on the date that such individual loses such eligibility and ends on the date specified by the Secretary.

''(c) STATE OPTION TO BUY-IN DUALLY ELIGIBLE INDIVIDUALS.—

''(1) COVERAGE OF PREMIUMS AS MEDICAL ASSISTANCE.—For purposes of applying the second sentence of section 1905(a), any reference to premiums under part B shall be considered to include a reference to premiums under this part.

''(2) STATE COMMITMENT TO CONTINUE PARTICIPATION IN PART D AFTER BENEFIT LIMIT REACHED.—As a condition of additional funding to a State under subsection (d), the State, in its State plan under title XIX, shall provide that in the case of any individual whose eligibility for medical assistance under title XIX is not limited to medicare cost-sharing and for whom the State elects to pay premiums under this part pursuant to this section, the State will purchase all prescription medicines for

such individual in accordance with the provisions of this part without regard to whether the benefit limit for such individual under section 1860B(b) has been reached.

''(3) MEDICARE COST-SHARING REQUIRED FOR QUALIFIED MEDICARE BENEFICIARIES.—In applying title XIX, the term 'medicare cost-sharing' (as defined in section 1905(p)(3)) is deemed to include—

''(A) premiums under section 1860D; and

''(B) the difference between the amount that is paid under section 1860B and the amount that would be paid under such section if any reference to '80 percent' in subsection (a)(2) of such section were deemed a reference to '100 percent' (or, if the Secretary approves a higher percentage under such section, if such percentage were deemed to be 100 percent).

''(d) PAYMENT TO STATES FOR COVERAGE OF CERTAIN MEDICARE COST-SHARING.—

''(1) IN GENERAL.—The Secretary shall provide for payment under this subsection to each State that provides for—

''(A) medicare cost-sharing described in section 1905(p)(3)(A)(ii) for individuals who would be qualified medicare beneficiaries de-

scribed in section 1905(p)(1) but for the fact that their income exceeds the income level established by the State under section 1905(p)(2) and is at least 120 percent, but less than 135 percent, of the official poverty line (referred to in such section) for a family of the size involved and who are not otherwise eligible for medical assistance under the State plan; and

''(B) medicare medicine cost-sharing (as defined in subsection (e)(2)) for qualified medicare medicine beneficiaries described in subsection (e)(1).

''(2) AMOUNT OF PAYMENT.—The amount of payment under paragraph (1) shall equal 100 percent of the cost-sharing described in such paragraph, except that, in the case of an individual whose eligibility for medical assistance under title XIX is not limited to medicare cost-sharing or medicare medicine cost-sharing, the amount of payment under paragraph (1)(B) shall be equal to the Federal medical assistance percentage described in section 1905(b)) of amounts as expended for such cost-sharing.

''(3) METHOD OF PAYMENT; RELATION TO OTHER PAYMENTS.—Amounts shall be paid to

States under this subsection in a manner similar to that provided under section 1903(d). Payments under this subsection shall be made in lieu of any payments that otherwise may be made for medical assistance provided under section 1902(a)(10)(E)(iv).

''(4) TREATMENT OF TERRITORIES.—

''(A) IN GENERAL.—Subject to subparagraph (B), this subsection shall not apply to States other than the 50 States and the District of Columbia.

''(B) PAYMENTS.—In the case of a State (other than the 50 States and the District of Columbia) that develops and implements a plan of assistance for pharmaceuticals provided to low-income medicare beneficiaries, the Secretary shall provide for payment to the State in an amount that is reasonable in relation to the payment levels provided to other States under paragraph (2).

''(e) DEFINITIONS; SPECIAL RULES.—For purposes of this section:

''(1) QUALIFIED MEDICARE MEDICINE BENEFICIARY.—The term 'qualified medicare medicine beneficiary' means an individual—

''(A) who is entitled to hospital insurance benefits under part A (including an individual entitled to such benefits pursuant to an enrollment under section 1818, but not including an individual entitled to such benefits only pursuant to an enrollment under section 1818A);

''(B) whose income (as determined under section 1612 for purposes of the supplemental security income program, except as provided in section 1905(p)(2)(D)) is above 100 percent but below 150 percent of the official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved; and

''(C) whose resources (as determined under section 1613 for purposes of the supplemental security income program) do not exceed twice the maximum amount of resources that an individual may have and obtain benefits under that program.

''(2) MEDICARE MEDICINE COST-SHARING.—The term 'medicare medicine cost-sharing' means the following costs incurred with respect to a quali-

fied medicare medicine beneficiary, without regard to whether the costs incurred were for items and services for which medical assistance is otherwise available under a State plan under title XIX:

"(A) In the case of a qualified medicare medicine beneficiary whose income (as determined under paragraph (1)) is less than 135 percent of the official poverty line—

"(i) premiums under section 1860D; and

"(ii) the difference between the amount that is paid under section 1860B and the amount that would be paid under such section if any reference to '50 percent' therein were deemed a reference to '100 percent' (or, if the Secretary approves a higher percentage under such section, if such percentage were deemed to be 100 percent).

"(B) In the case of a qualified medicare medicine beneficiary whose income (as determined under paragraph (1)) is at least 135 percent but less than 150 percent of the official poverty line, a percentage of premiums under section 1860D, determined on a linear sliding

scale ranging from 100 percent for individuals with incomes at 135 percent of such line to 0 percent for individuals with incomes at 150 percent of such line.

''(3) STATE.—The term 'State' has the meaning given such term under section 1101(a) for purposes of title XIX.

''(4) TREATMENT OF DRUGS PURCHASED.—The provisions of section 1927 shall not apply to prescription drugs purchased under this part pursuant to an agreement with the Secretary under this section (including any drugs so purchased after the limit under section 1860B(b) has been exceeded).

''PRESCRIPTION MEDICINE INSURANCE ACCOUNT

''SEC. 1860F. (a) ESTABLISHMENT.—There is created within the Federal Supplemental Medical Insurance Trust Fund established by section 1841 an account to be known as the 'Prescription Medicine Insurance Account' (in this section referred to as the 'Account').

''(b) AMOUNTS IN ACCOUNT.—

''(1) IN GENERAL.—The Account shall consist of—

''(A) such amounts as may be deposited in, or appropriated to, such fund as provided in this part; and

''(B) such gifts and bequests as may be made as provided in section 201(i)(1).

''(2) SEPARATION OF FUNDS.—Funds provided under this part to the Account shall be kept separate from all other funds within the Federal Supplemental Medical Insurance Trust Fund.

''(c) PAYMENTS FROM ACCOUNT.—The Managing Trustee shall pay from time to time from the Account such amounts as the Secretary certifies are necessary to make the payments provided for by this part, and the payments with respect to administrative expenses in accordance with section 201(g).

''ADMINISTRATION OF BENEFITS

''SEC. 1860G. (a) THROUGH HCFA.—The Secretary shall provide for administration of the benefits under this part through the Health Care Financing Administration in accordance with the provisions of this section. The Administrator of such Administration may enter into contracts with carriers to administer this part in the same manner as the Administrator enters into such contracts to administer part B. Any such contract shall be separate from any contract under section 1842.

''(b) ADMINISTRATION FUNCTIONS.—In carrying out this part, the Administrator (or a carrier under a contract with the Administrator) shall (or in the case of the func-

tion described in paragraph (9), may) perform the following functions:

"(1) PARTICIPATION AGREEMENTS, PRICES, AND FEES.—

"(A) NEGOTIATED PRICES.—Establish, through negotiations with medicine manufacturers and wholesalers and pharmacies, a schedule of prices for covered prescription medicines.

"(B) AGREEMENTS WITH PHARMACIES.—Enter into participation agreements under subsection (c) with pharmacies, that include terms that—

"(i) secure the participation of sufficient numbers of pharmacies to ensure convenient access (including adequate emergency access);

"(ii) permit the participation of any pharmacy in the service area that meets the participation requirements described in subsection (c); and

"(iii) allow for reasonable dispensing and consultation fees for pharmacies.

"(C) LISTS OF PRICES AND PARTICIPATING PHARMACIES.—Ensure that the negotiated prices established under subparagraph (A) and

the list of pharmacies with agreements under subsection (c) are regularly updated and readily available to health care professionals authorized to prescribe medicines, participating pharmacies, and enrolled individuals.

''(2) TRACKING OF COVERED ENROLLED INDIVIDUALS.—Maintain accurate, updated records of all enrolled individuals (other than individuals enrolled in a plan under part C).

''(3) PAYMENT AND COORDINATION OF BENEFITS.—

''(A) PAYMENT.—

''(i) Administer claims for payment of benefits under this part and encourage, to the maximum extent possible, use of electronic means for the submissions of claims.

''(ii) Determine amounts of benefit payments to be made.

''(iii) Receive, disburse, and account for funds used in making such payments, including through the activities specified in the provisions of this paragraph.

''(B) COORDINATION.—Coordinate with other private benefit providers, pharmacies, and other relevant entities as necessary to ensure

appropriate coordination of benefits with respect to enrolled individuals, including coordination of access to and payment for covered prescription medicines according to an individual's in-service area plan provisions, when such individual is traveling outside the home service area, and under such other circumstances as the Secretary may specify.

''(C) EXPLANATION OF BENEFITS.—Furnish to enrolled individuals an explanation of benefits in accordance with section 1806(a), and a notice of the balance of benefits remaining for the current year, whenever prescription medicine benefits are provided under this part (except that such notice need not be provided more often than monthly).

''(4) RULES RELATING TO PROVISION OF BENEFITS.—

''(A) IN GENERAL.—In providing benefits under this part, the Secretary (directly or through contracts) shall employ mechanisms to provide benefits economically, including the use of—

''(i) formularies (consistent with subparagraph (B));

''(ii) automatic generic medicine substitution (unless the physician specifies otherwise, in which case a 30-day prescription may be dispensed pending a consultation with the physician on whether a generic substitute can be dispensed in the future);

''(iii) tiered copayments (which may include copayments at a rate lower than 20 percent) to encourage the use of the lowest cost, on-formulary product in cases where there is no restrictive prescription (described in subparagraph (D)(i)); and

''(iv) therapeutic interchange.

''(B) REQUIREMENTS WITH RESPECT TO FORMULARIES.—If a formulary is used to contain costs under this part—

''(i) use an advisory committee (or a therapeutics committee) comprised of licensed practicing physicians, pharmacists, and other health care practitioners to develop and manage the formulary;

''(ii) include in the formulary at least 1 medicine from each therapeutic class

and, if available, a generic equivalent thereof; and

''(iii) disclose to current and prospective enrollees and to participating providers and pharmacies, the nature of the formulary restrictions, including information regarding the medicines included in the formulary and any difference in cost-sharing amounts.

''(C) CONSTRUCTION.—Nothing in this subsection shall be construed to prevent the Secretary (directly or through contracts) from using incentives (including a lower beneficiary coinsurance) to encourage enrollees to select generic or other cost-effective medicines, so long as—

''(i) such incentives are designed not to result in any increase in the aggregate expenditures under the Federal Medicare Prescription Medicine Trust Fund;

''(ii) the average coinsurance charged to all beneficiaries by the Secretary (directly or through contractors) shall seek to approximate (but in no case exceed) 20 percent for on-formulary medicines;

''(iii) a beneficiary's coinsurance shall be no greater than 20 percent if the prescription is a restrictive prescription; and

''(iv) the reimbursement for a prescribed nonformulary medicine without a restrictive prescription in no case shall be more than the lowest reimbursement for a formulary medicine in the therapeutic class of the prescribed medicine.

''(D) RESTRICTIVE PRESCRIPTION.—For purposes of this section:

''(i) WRITTEN PRESCRIPTIONS.—In the case of a written prescription for a medicine, it is a restrictive prescription only if the prescription indicates, in the writing of the physician or other qualified person prescribing the medicine and with an appropriate phrase (such as 'brand medically necessary') recognized by the Secretary, that a particular medicine product must be dispensed based upon a belief by the physician or person prescribing the medicine that the particular medicine will provide even marginally superior therapeutic benefits to the individual for whom

the medicine is prescribed or would have marginally fewer adverse reactions with respect to such individual.

''(ii) TELEPHONE PRESCRIPTIONS.—In the case of a prescription issued by telephone for a medicine, it is a restrictive prescription only if the prescription cannot be longer than 30 days and the physician or other qualified person prescribing the medicine (through use of such an appropriate phrase) states that a particular medicine product must be dispensed, and the physician or other qualified person submits to the pharmacy involved, within 30 days after the date of the telephone prescription, a written confirmation from the physician or other qualified person prescribing the medicine and which indicates with such appropriate phrase that the particular medicine product was required to have been dispensed based upon a belief by the physician or person prescribing the medicine that the particular medicine will provide even marginally superior therapeutic benefits to the individual for whom

the medicine is prescribed or would have marginally fewer adverse reactions with respect to such individual. Such written confirmation is required to refill the prescription.

''(iii) REVIEW OF RESTRICTIVE PRESCRIPTIONS.—The advisory committee (established under subparagraph (B)(i)) may decide to review a restrictive prescription and, if so, it may approve or disapprove such restrictive prescription. It may not disapprove such restrictive prescription unless it finds that there is no clinical evidence or peer reviewed medical literature that supports a determination that the particular medicine provides even marginally superior therapeutic benefits to the individual for whom the medicine is prescribed or would have marginally fewer adverse reactions with respect to such individual. If it disapproves, upon request of the prescribing physician or the enrollee, the committee must provide for a review by an independent contractor of such decision within 48 hours of the time of submission

of the prescription, to determine whether the prescription is an eligible benefit under this part. The Secretary shall ensure that independent contractors so used are completely independent of the contractor or its advisory committee.

''(5) COST AND UTILIZATION MANAGEMENT; QUALITY ASSURANCE.—Have in place effective cost and utilization management, drug utilization review, quality assurance measures, and systems to reduce medical errors, including at least the following, together with such additional measures as the Administrator may specify:

''(A) DRUG UTILIZATION REVIEW.—A drug utilization review program conforming to the standards provided in section 1927(g)(2) (with such modifications as the Administrator finds appropriate).

''(B) FRAUD AND ABUSE CONTROL.—Activities to control fraud, abuse, and waste, including prevention of diversion of pharmaceuticals to the illegal market.

''(C) MEDICATION THERAPY MANAGEMENT.—

''(i) IN GENERAL.—A program of medicine therapy management and medication administration that is designed to assure that covered outpatient medicines are appropriately used to achieve therapeutic goals and reduce the risk of adverse events, including adverse drug interactions.

''(ii) ELEMENTS.—Such program may include—

''(I) enhanced beneficiary understanding of such appropriate use through beneficiary education, counseling, and other appropriate means; and

''(II) increased beneficiary adherence with prescription medication regimens through medication refill reminders, special packaging, and other appropriate means.

''(iii) DEVELOPMENT OF PROGRAM IN COOPERATION WITH LICENSED PHARMACISTS.—The program shall be developed in cooperation with licensed pharmacists and physicians.

''(iv) CONSIDERATIONS IN PHARMACY FEES.—There shall be taken into account, in establishing fees for pharmacists and others providing services under the medication therapy management program, the resources and time used in implementing the program.

''(6) EDUCATION AND INFORMATION ACTIVITIES.—Have in place mechanisms for disseminating educational and informational materials to enrolled individuals and health care providers designed to encourage effective and cost-effective use of prescription medicine benefits and to ensure that enrolled individuals understand their rights and obligations under the program.

''(7) BENEFICIARY PROTECTIONS.—

''(A) CONFIDENTIALITY OF HEALTH INFORMATION.—Have in effect systems to safeguard the confidentiality of health care information on enrolled individuals, which comply with section 1106 and with section 552a of title 5, United States Code, and meet such additional standards as the Administrator may prescribe.

"(B) GRIEVANCE AND APPEAL PROCEDURES.—Have in place such procedures as the Administrator may specify for hearing and resolving grievances and appeals, including expedited appeals, brought by enrolled individuals against the Administrator or a pharmacy concerning benefits under this part, which shall include procedures equivalent to those specified in subsections (f) and (g) of section 1852.

"(8) RECORDS, REPORTS, AND AUDITS.—

"(A) RECORDS AND AUDITS.—Maintain adequate records, and afford the Administrator access to such records (including for audit purposes).

"(B) REPORTS.—Make such reports and submissions of financial and utilization data as the Administrator may require taking into account standard commercial practices.

"(9) PROPOSAL FOR ALTERNATIVE COINSURANCE AMOUNT.—

"(A) SUBMISSION.—The Administrator may provide for increased Government cost-sharing for generic prescription medicines, prescription medicines on a formulary, or prescrip-

tion medicines obtained through mail order pharmacies.

''(B) CONTENTS.—The proposal submitted under subparagraph (A) shall contain evidence that such increased cost-sharing would not result in an increase in aggregate costs to the Account, including an analysis of differences in projected drug utilization patterns by beneficiaries whose cost-sharing would be reduced under the proposal and those making the cost-sharing payments that would otherwise apply.

''(10) OTHER REQUIREMENTS.—Meet such other requirements as the Secretary may specify.

The Administrator shall negotiate a schedule of prices under paragraph (1)(A), except that nothing in this sentence shall prevent a carrier under a contract with the Administrator from negotiating a lower schedule of prices for covered prescription medicines.

''(c) PHARMACY PARTICIPATION AGREEMENTS.—

''(1) IN GENERAL.—A pharmacy that meets the requirements of this subsection shall be eligible to enter an agreement with the Administrator to furnish covered prescription medicines and pharmacists' services to enrolled individuals.

''(2) TERMS OF AGREEMENT.—An agreement under this subsection shall include the following terms and requirements:

''(A) LICENSING.—The pharmacy and pharmacists shall meet (and throughout the contract period will continue to meet) all applicable State and local licensing requirements.

''(B) LIMITATION ON CHARGES.—Pharmacies participating under this part shall not charge an enrolled individual more than the negotiated price for an individual medicine as established under subsection (b)(1), regardless of whether such individual has attained the benefit limit under section 1860B(b), and shall not charge an enrolled individual more than the individual's share of the negotiated price as determined under the provisions of this part.

''(C) PERFORMANCE STANDARDS.—The pharmacy and the pharmacist shall comply with performance standards relating to—

''(i) measures for quality assurance, reduction of medical errors, and participation in the drug utilization review program described in subsection (b)(3)(A);

"(ii) systems to ensure compliance with the confidentiality standards applicable under subsection (b)(5)(A); and

"(iii) other requirements as the Secretary may impose to ensure integrity, efficiency, and the quality of the program.

"(D) DISCLOSURE OF PRICE OF GENERIC MEDICINE.—A pharmacy participating under this part shall inform an enrollee of the difference in price between generic and nongeneric equivalents.

"(d) SPECIAL ATTENTION TO RURAL AND HARD-TO-SERVE AREAS.—

"(1) IN GENERAL.—The Secretary shall ensure that all beneficiaries have access to the full range of pharmaceuticals under this part, and shall give special attention to access, pharmacist counseling, and delivery in rural and hard-to-serve areas (as the Secretary may define by regulation).

"(2) SPECIAL ATTENTION DEFINED.—For purposes of paragraph (1), the term 'special attention' may include bonus payments to retail pharmacists in rural areas and any other actions the Secretary determines are necessary to ensure full access to rural and hard-to-serve beneficiaries.

''(3) GAO REPORT.—Not later than 2 years after the implementation of this part the Comptroller General of the United States shall submit to Congress a report on the access of medicare beneficiaries to pharmaceuticals and pharmacists' services in rural and hard-to-serve areas under this part together with any recommendations of the Comptroller General regarding any additional steps the Secretary may need to take to ensure the access of medicare beneficiaries to pharmaceuticals and pharmacists' services in such areas under this part.

''(e) INCENTIVES FOR COST AND UTILIZATION MANAGEMENT AND QUALITY IMPROVEMENT.—The Secretary is authorized to include in a contract awarded under subsection (b) with a carrier such incentives for cost and utilization management and quality improvement as the Secretary may deem appropriate, including—

''(1) bonus and penalty incentives to encourage administrative efficiency;

''(2) incentives under which carriers share in any benefit savings achieved;

''(3) risk-sharing arrangements related to initiatives to encourage savings in benefit payments;

''(4) financial incentives under which savings derived from the substitution of generic medicines in

lieu of nongeneric medicines are made available to carriers, pharmacies, and the Prescription Medicine Insurance Account; and

''(5) any other incentive that the Secretary deems appropriate and likely to be effective in managing costs or utilization.

''EMPLOYER INCENTIVE PROGRAM FOR EMPLOYMENT-BASED RETIREE MEDICINE COVERAGE

''SEC. 1860H. (a) PROGRAM AUTHORITY.—The Secretary shall develop and implement a program under this section called the 'Employer Incentive Program' that encourages employers and other sponsors of employment-based health care coverage to provide adequate prescription medicine benefits to retired individuals and to maintain such existing benefit programs, by subsidizing, in part, the sponsor's cost of providing coverage under qualifying plans.

''(b) SPONSOR REQUIREMENTS.—In order to be eligible to receive an incentive payment under this section with respect to coverage of an individual under a qualified retiree prescription medicine plan (as defined in subsection (f)(3)), a sponsor shall meet the following requirements:

''(1) ASSURANCES.—The sponsor shall—

''(A) annually attest, and provide such assurances as the Secretary may require, that the coverage offered by the sponsor is a qualified

retiree prescription medicine plan, and will remain such a plan for the duration of the sponsor's participation in the program under this section; and

"(B) guarantee that it will give notice to the Secretary and covered retirees—

"(i) at least 120 days before terminating its plan; and

"(ii) immediately upon determining that the actuarial value of the prescription medicine benefit under the plan falls below the actuarial value of the insurance benefit under this part.

"(2) OTHER REQUIREMENTS.—The sponsor shall provide such information, and comply with such requirements, including information requirements to ensure the integrity of the program, as the Secretary may find necessary to administer the program under this section.

"(c) INCENTIVE PAYMENT.—

"(1) IN GENERAL.—A sponsor that meets the requirements of subsection (b) with respect to a quarter in a calendar year shall have payment made by the Secretary on a quarterly basis (to the sponsor or, at the sponsor's direction, to the appropriate em-

ployment-based health plan) of an incentive payment, in the amount determined as described in paragraph (2), for each retired individual (or spouse) who—

"(A) was covered under the sponsor's qualified retiree prescription medicine plan during such quarter; and

"(B) was eligible for but was not enrolled in the insurance program under this part.

"(2) AMOUNT OF INCENTIVE.—The payment under this section with respect to each individual described in paragraph (1) for a month shall be equal to ⅔ of the monthly premium amount payable from the Prescription Medicine Insurance Account for an enrolled individual, as set for the calendar year pursuant to section 1860D(a)(2).

"(3) PAYMENT DATE.—The incentive under this section with respect to a calendar quarter shall be payable as of the end of the next succeeding calendar quarter.

"(d) CIVIL MONEY PENALTIES.—A sponsor, health plan, or other entity that the Secretary determines has, directly or through its agent, provided information in connection with a request for an incentive payment under this section that the entity knew or should have known to be

false shall be subject to a civil monetary penalty in an amount equal to $2,000 for each false representation plus an amount not to exceed 3 times the total incentive amounts under subsection (c) that were paid (or would have been payable) on the basis of such information.

''(e) PART D ENROLLMENT FOR CERTAIN INDIVIDUALS COVERED BY EMPLOYMENT-BASED RETIREE HEALTH COVERAGE PLANS.—

''(1) ELIGIBLE INDIVIDUALS.—An individual shall be given the opportunity to enroll in the program under this part during the period specified in paragraph (2) if—

''(A) the individual declined enrollment in the program under this part at the time the individual first satisfied section 1860C(a);

''(B) at that time, the individual was covered under a qualified retiree prescription medicine plan for which an incentive payment was paid under this section; and

''(C)(i) the sponsor subsequently ceased to offer such plan; or

''(ii) the value of prescription medicine coverage under such plan is reduced below the value of the coverage provided at the time the

individual first became eligible to participate in the program under this part.

''(2) SPECIAL ENROLLMENT PERIOD.—An individual described in paragraph (1) shall be eligible to enroll in the program under this part during the 6-month period beginning on the first day of the month in which—

''(A) the individual receives a notice that coverage under such plan has terminated (in the circumstance described in paragraph (1)(C)(i)) or notice that a claim has been denied because of such a termination; or

''(B) the individual received notice of the change in benefits (in the circumstance described in paragraph (1)(C)(ii)).

''(f) DEFINITIONS.—In this section:

''(1) EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.—The term 'employment-based retiree health coverage' means health insurance or other coverage of health care costs for retired individuals (or for such individuals and their spouses and dependents) based on their status as former employees or labor union members.

''(2) EMPLOYER.—The term 'employer' has the meaning given to such term by section 3(5) of the

Employee Retirement Income Security Act of 1974 (except that such term shall include only employers of 2 or more employees).

''(3) QUALIFIED RETIREE PRESCRIPTION MEDICINE PLAN.—The term 'qualified retiree prescription medicine plan' means health insurance coverage included in employment-based retiree health coverage that—

''(A) provides coverage of the cost of prescription medicines whose actuarial value to each retired beneficiary equals or exceeds the actuarial value of the benefits provided to an individual enrolled in the program under this part; and

''(B) does not deny, limit, or condition the coverage or provision of prescription medicine benefits for retired individuals based on age or any health status-related factor described in section 2702(a)(1) of the Public Health Service Act.

''(4) SPONSOR.—The term 'sponsor' has the meaning given the term 'plan sponsor' by section 3(16)(B) of the Employee Retirement Income Security Act of 1974.

''PROMOTION OF PHARMACEUTICAL RESEARCH ON BREAK-THROUGH MEDICINES WHILE PROVIDING PROGRAM COST CONTAINMENT

''SEC. 1860I. (a) MONITORING EXPENDITURES.—The Secretary shall monitor expenditures under this part. On October 1, 2003, the Secretary shall estimate total expenditures under this part for 2003.

''(b) ESTABLISHMENT OF SUSTAINABLE GROWTH RATE.—

''(1) IN GENERAL.—The Secretary shall establish a sustainable growth rate prescription medicine target system for expenditures under this part for each year after 2003.

''(2) INITIAL COMPUTATION.—Such target shall equal the amount of total expenditures estimated for 2003 adjusted by the Secretary's estimate of a sustainable growth rate (in this section referred to as an 'SGR') percentage between 2003 and 2004. Such SGR shall be estimated based on the following:

''(A) Reasonable changes in the cost of production or price of covered pharmaceuticals, but in no event more than the rate of increase in the Consumer Price Index for all urban consumers for the period involved.

"(B) Population enrolled in this part, both in numbers and in average age and severity of chronic and acute illnesses.

"(C) Appropriate changes in utilization of pharmaceuticals, as determined by the Drug Review Board (established under subsection (c)(3)) and based on best estimates of utilization change if there were no direct-to-consumer advertising or promotions to providers.

"(D) Productivity index of manufacturers and distributors.

"(E) Percentage of products with patent and market exclusivity protection versus products without patent protection and changes in the availability of generic substitutes.

"(F) Such other factors as the Secretary may determine are appropriate.

In no event may the sustainable growth rate exceed 120 percent of the estimated per capita growth in total spending under this title.

"(3) COMPUTATION FOR SUBSEQUENT YEARS.—In October of 2004 and each year thereafter, for purposes of setting the SGRs for the succeeding year, the Secretary shall adjust each current year's estimated expenditures by the estimated SGR

for the succeeding year, further adjusted for corrections in earlier estimates and the receipt of additional data on previous years spending as follows:

"(A) ERROR ESTIMATES.—An adjustment (up or down) for errors in the estimate of total expenditures under this part for the previous year.

"(B) COSTS.—An adjustment (up or down) for corrections in the cost of production of prescriptions covered under this part between the current calendar year and the previous year.

"(C) TARGET.—An adjustment for any amount (over or under) that expenditures in the current year under this part are estimated to differ from the target amount set for the year. If expenditures in the current year are estimated to be—

"(i) less than the target amount, future target amounts will be adjusted downward; or

"(ii) more than the target amount, the Secretary shall notify all pharmaceutical manufacturers with sales of pharmaceutical prescription medicine products to medicare beneficiaries under this part,

of a rebate requirement (except as provided in this subparagraph) to be deposited in the Federal Medicare Prescription Medicine Trust Fund.

''(D) REBATE DETERMINATION.—The amount of the rebate described in subparagraph (C)(ii) may vary among manufacturers and shall be based on the manufacturer's estimated contribution to the expenditure above the target amount, taking into consideration such factors as—

''(i) above average increases in the cost of the manufacturer's product;

''(ii) increases in utilization due to promotion activities of the manufacturer, wholesaler, or retailer;

''(iii) launch prices of new drugs at the same or higher prices as similar drugs already in the marketplace (so-called 'me too' or 'copy-cat' drugs);

''(iv) the role of the manufacturer in delaying the entry of generic products into the market; and

''(v) such other actions by the manufacturer that the Secretary may determine

has contributed to the failure to meet the SGR target.

The rebates shall be established under such subparagraph so that the total amount of the rebates is estimated to ensure that the amount the target for the current year is estimated to be exceeded is recovered in lower spending in the subsequent year; except that, no rebate shall be made in any manufacturer's product which the Food and Drug Administration has determined is a breakthrough medicine (as determined under subsection (c)) or an orphan medicine.

''(c) BREAKTHROUGH MEDICINES.—

''(1) DETERMINATION.—For purposes of this section, a medicine is a 'breakthrough medicine' if the Drug Review Board (established under paragraph (3)) determines—

''(A) it is a new product that will make a significant and major improvement by reducing physical or mental illness, reducing mortality, or reducing disability; and

''(B) that no other product is available to beneficiaries that achieves similar results for the same condition at a lower cost.

''(2) CONDITION.—An exemption from rebates under subsection (b)(3) for a breakthrough medicine shall continue as long as the medicine is certified as a breakthrough medicine but shall be limited to 7 calendar years from 2003 or 7 calendar years from the date of the initial determination under paragraph (1), whichever is later.

''(3) DRUG REVIEW BOARD.—The Drug Review Board under this paragraph shall consist of the Commissioner of Food and Drugs, the Directors of the National Institutes of Health, the Director of the National Science Foundation, and 10 experts in pharmaceuticals, medical research, and clinical care, selected by the Commissioner of Food and Drugs from the faculty of academic medical centers, except that no person who has (or who has an immediate family member that has) any conflict of interest with any pharmaceutical manufacturer shall serve on the Board.

''(d) NO REVIEW.—The Secretary's determination of the rebate amounts under this section, and the Drug Review Board's determination of what is a breakthrough drug, are not subject to administrative or judicial review.

''APPROPRIATIONS TO COVER GOVERNMENT CONTRIBUTIONS

''SEC. 1860J. (a) IN GENERAL.—There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, to the Prescription Medicine Insurance Account, a Government contribution equal to—

''(1) the aggregate premiums payable for a month pursuant to section 1860D(a)(2) by individuals enrolled in the program under this part; plus

''(2) one-half the aggregate premiums payable for a month pursuant to such section for such individuals by former employers; plus

''(3) the benefits payable by reason of the application of paragraph (2) of section 1860B(a) (relating to catastrophic benefits).

''(b) APPROPRIATIONS TO COVER INCENTIVES FOR EMPLOYMENT-BASED RETIREE MEDICINE COVERAGE.—There are authorized to be appropriated to the Prescription Medicine Insurance Account from time to time, out of any moneys in the Treasury not otherwise appropriated, such sums as may be necessary for payment of incentive payments under section 1860H(c).

''PRESCRIPTION MEDICINE DEFINED

''SEC. 1860K. As used in this part, the term 'prescription medicine' means—

''(1) a drug that may be dispensed only upon a prescription, and that is described in subparagraph (A)(i), (A)(ii), or (B) of section 1927(k)(2); and

''(2) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act, and needles, syringes, and disposable pumps for the administration of such insulin.''.

(b) CONFORMING AMENDMENTS.—

(1) AMENDMENTS TO FEDERAL SUPPLEMENTARY HEALTH INSURANCE TRUST FUND.—Section 1841 of the Social Security Act (42 U.S.C. 1395t) is amended—

(A) in the last sentence of subsection (a)—

(i) by striking ''and'' after ''section 201(i)(1)''; and

(ii) by inserting before the period the following: '', and such amounts as may be deposited in, or appropriated to, the Prescription Medicine Insurance Account established by section 1860F'';

(B) in subsection (g), by inserting after ''by this part,'' the following: ''the payments provided for under part D (in which case the payments shall come from the Prescription

Medicine Insurance Account in the Supplementary Medical Insurance Trust Fund),'';

(C) in the first sentence of subsection (h), by inserting before the period the following: ''and section 1860D(b)(4) (in which case the payments shall come from the Prescription Medicine Insurance Account in the Supplementary Medical Insurance Trust Fund)''; and

(D) in the first sentence of subsection (i)—

(i) by striking ''and'' after ''section 1840(b)(1)''; and

(ii) by inserting before the period the following: '', section 1860D(b)(2) (in which case the payments shall come from the Prescription Medicine Insurance Account in the Supplementary Medical Insurance Trust Fund)''.

(2) PRESCRIPTION MEDICINE OPTION UNDER MEDICARE+CHOICE PLANS.—

(A) ELIGIBILITY, ELECTION, AND ENROLLMENT.—Section 1851 of the Social Security Act (42 U.S.C. 1395w–21) is amended—

(i) in subsection (a)(1)(A), by striking ''parts A and B'' and inserting ''parts A, B, and D''; and

(ii) in subsection (i)(1), by striking ''parts A and B'' and inserting ''parts A, B, and D''.

(B) VOLUNTARY BENEFICIARY ENROLLMENT FOR MEDICINE COVERAGE.—Section 1852(a)(1)(A) of such Act (42 U.S.C. 1395w–22(a)(1)(A)) is amended by inserting ''(and under part D to individuals also enrolled under that part)'' after ''parts A and B''.

(C) ACCESS TO SERVICES.—Section 1852(d)(1) of such Act (42 U.S.C. 1395w–22(d)(1)) is amended—

(i) in subparagraph (D), by striking ''and'' at the end;

(ii) in subparagraph (E), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following new subparagraph:

''(F) the plan for prescription medicine benefits under part D guarantees coverage of any specifically named covered prescription

medicine for an enrollee, when prescribed by a physician in accordance with the provisions of such part, regardless of whether such medicine would otherwise be covered under an applicable formulary or discount arrangement.''.

(D) PAYMENTS TO ORGANIZATIONS.—Section 1853(a)(1)(A) of such Act (42 U.S.C. 1395w–23(a)(1)(A)) is amended—

(i) by inserting ''determined separately for benefits under parts A and B and under part D (for individuals enrolled under that part)'' after ''as calculated under subsection (c)'';

(ii) by striking ''that area, adjusted for such risk factors'' and inserting ''that area. In the case of payment for benefits under parts A and B, such payment shall be adjusted for such risk factors as''; and

(iii) by inserting before the last sentence the following: ''In the case of the payments for benefits under part D, such payment shall initially be adjusted for the risk factors of each enrollee as the Secretary determines to be feasible and appropriate. By 2006, the adjustments would be

for the same risk factors applicable for benefits under parts A and B.''.

(E) CALCULATION OF ANNUAL MEDICARE +CHOICE CAPITATION RATES.—Section 1853(c) of such Act (42 U.S.C. 1395w–23(c)) is amended—

(i) in paragraph (1), in the matter preceding subparagraph (A), by inserting ''for benefits under parts A and B'' after ''capitation rate'';

(ii) in paragraph (6)(A), by striking ''rate of growth in expenditures under this title'' and inserting ''rate of growth in expenditures for benefits available under parts A and B''; and

(iii) by adding at the end the following new paragraph:

''(8) PAYMENT FOR PRESCRIPTION MEDICINES.—The Secretary shall determine a capitation rate for prescription medicines—

''(A) dispensed in 2003, which is based on the projected national per capita costs for prescription medicine benefits under part D and associated claims processing costs for bene-

ficiaries under the original medicare fee-for-service program; and

''(B) dispensed in each subsequent year, which shall be equal to the rate for the previous year updated by the Secretary's estimate of the projected per capita rate of growth in expenditures under this title for an individual enrolled under part D.''.

(F) LIMITATION ON ENROLLEE LIABILITY.—Section 1854(e) of such Act (42 U.S.C. 1395w–24(e)) is amended by adding at the end the following new paragraph:

''(5) SPECIAL RULE FOR PROVISION OF PART D BENEFITS.—In no event may a Medicare+Choice organization include as part of a plan for prescription medicine benefits under part D a requirement that an enrollee pay a deductible, or a coinsurance percentage that exceeds 20 percent.''.

(G) REQUIREMENT FOR ADDITIONAL BENEFITS.—Section 1854(f)(1) of such Act (42 U.S.C. 1395w–24(f)(1)) is amended by adding at the end the following new sentence: ''Such determination shall be made separately for benefits under parts A and B and for prescription medicine benefits under part D.''.

(3) EXCLUSIONS FROM COVERAGE.—

(A) APPLICATION TO PART D.—Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)) is amended in the matter preceding paragraph (1) by striking ''part A or part B'' and inserting ''part A, B, or D''.

(B) PRESCRIPTION MEDICINES NOT EXCLUDED FROM COVERAGE IF APPROPRIATELY PRESCRIBED.—Section 1862(a)(1) of such Act (42 U.S.C. 1395y(a)(1)) is amended—

(i) in subparagraph (H), by striking ''and'' at the end;

(ii) in subparagraph (I), by striking the semicolon at the end and inserting '', and''; and

(iii) by adding at the end the following new subparagraph:

''(J) in the case of prescription medicines covered under part D, which are not prescribed in accordance with such part;''.

**SEC. 4. SUBSTANTIAL REDUCTIONS IN THE PRICE OF PRESCRIPTION DRUGS FOR MEDICARE BENEFICIARIES.**

(a) PARTICIPATING MANUFACTURERS.—

(1) IN GENERAL.—Each participating manufacturer of a covered outpatient drug shall make available for purchase by each pharmacy such covered outpatient drug in the amount described in paragraph (2) at the price described in paragraph (3).

(2) DESCRIPTION OF AMOUNT OF DRUGS.—The amount of a covered outpatient drug that a participating manufacturer shall make available for purchase by a pharmacy is an amount equal to the aggregate amount of the covered outpatient drug sold or distributed by the pharmacy to medicare beneficiaries.

(3) DESCRIPTION OF PRICE.—The price at which a participating manufacturer shall make a covered outpatient drug available for purchase by a pharmacy is the price equal to the lowest of the following:

(A) The lowest price paid for the covered outpatient drug by any agency or department of the United States.

(B) The manufacturer's best price for the covered outpatient drug, as defined in section 1927(c)(1)(C) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)).

(C) The lowest price at which the drug is available (as determined by the Secretary) through importation consistent with the provisions of section 804 of the Federal Food, Drug, and Cosmetic Act.

(b) SPECIAL PROVISION WITH RESPECT TO HOSPICE PROGRAMS.—For purposes of determining the amount of a covered outpatient drug that a participating manufacturer shall make available for purchase by a pharmacy under subsection (a), there shall be included in the calculation of such amount the amount of the covered outpatient drug sold or distributed by a pharmacy to a hospice program. In calculating such amount, only amounts of the covered outpatient drug furnished to a medicare beneficiary enrolled in the hospice program shall be included.

(c) ADMINISTRATION.—The Secretary shall issue such regulations as may be necessary to implement this section.

(d) REPORTS TO CONGRESS REGARDING EFFECTIVENESS OF SECTION.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, and annually thereafter, the Secretary shall report to Congress regarding the effectiveness of this section in—

(A) protecting medicare beneficiaries from discriminatory pricing by drug manufacturers; and

(B) making prescription drugs available to medicare beneficiaries at substantially reduced prices.

(2) CONSULTATION.—In preparing such reports, the Secretary shall consult with public health experts, affected industries, organizations representing consumers and older Americans, and other interested persons.

(3) RECOMMENDATIONS.—The Secretary shall include in such reports any recommendations they consider appropriate for changes in this section to further reduce the cost of covered outpatient drugs to medicare beneficiaries.

(e) DEFINITIONS.—For purposes of this section:

(1) PARTICIPATING MANUFACTURER.—The term ''participating manufacturer'' means any manufacturer of drugs or biologicals that, on or after the date of enactment of this Act, enters into a contract or agreement with the United States for the sale or distribution of covered outpatient drugs to the United States.

(2) COVERED OUTPATIENT DRUG.—The term ''covered outpatient drug'' has the meaning given that term in section 1927(k)(2) of the Social Security Act (42 U.S.C. 1396r–8(k)(2)).

(3) MEDICARE BENEFICIARY.—The term ''medicare beneficiary'' means an individual entitled to benefits under part A of title XVIII of the Social Security Act or enrolled under part B of such title, or both.

(4) HOSPICE PROGRAM.—The term ''hospice program'' has the meaning given that term under section 1861(dd)(2) of the Social Security Act (42 U.S.C. 1395x(dd)(2)).

(5) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(f) EFFECTIVE DATE.—The Secretary shall implement this section as expeditiously as practicable and in a manner consistent with the obligations of the United States.

**SEC. 5. AMENDMENTS TO PROGRAM FOR IMPORTATION OF CERTAIN PRESCRIPTION DRUGS BY PHARMACISTS AND WHOLESALERS.**

Section 804 of the Federal Food, Drug, and Cosmetic Act (as added by section 745(c)(2) of Public Law 106–387) is amended—

(1) by striking subsections (e) and (f) and inserting the following subsections:

''(e) TESTING; APPROVED LABELING.—

''(1) TESTING.—Regulations under subsection (a)—

''(A) shall require that testing referred to in paragraphs (6) through (8) of subsection (d) be conducted by the importer of the covered product pursuant to subsection (a), or the manufacturer of the product;

''(B) shall require that, if such tests are conducted by the importer, information needed to authenticate the product being tested be supplied by the manufacturer of such product to the importer; and

''(C) shall provide for the protection of any information supplied by the manufacturer under subparagraph (B) that is a trade secret or commercial or financial information that is privileged or confidential.

''(2) APPROVED LABELING.—For purposes of importing a covered product pursuant to subsection (a), the importer involved may use the labeling approved for the product under section 505, notwithstanding any other provision of law.

''(f) DISCRETION OF SECRETARY REGARDING TESTING.—The Secretary may waive or modify testing requirements described in subsection (d) if, with respect to specific countries or specific distribution chains, the Secretary has entered into agreements or otherwise approved arrangements that the Secretary determines ensure that the covered products involved are not adulterated or in violation of section 505.'';

(2) by striking subsections (h) and (i) and inserting the following subsections:

''(h) PROHIBITED AGREEMENTS; NONDISCRIMINATION.—

''(1) PROHIBITED AGREEMENTS.—No manufacturer of a covered product may enter into a contract or agreement that includes a provision to prevent the sale or distribution of covered products imported pursuant to subsection (a).

''(2) NONDISCRIMINATION.—No manufacturer of a covered product may take actions that discriminate against, or cause other persons to discriminate against, United States pharmacists, wholesalers, or consumers regarding the sale or distribution of covered products.

''(i) STUDY AND REPORT.—

''(1) STUDY.—The Comptroller General of the United States shall conduct a study on the imports permitted under this section, taking into consideration the information received under subsection (a). In conducting such study, the Comptroller General shall—

''(A) evaluate importers' compliance with regulations, determine the number of shipments, if any, permitted under this section that have been determined to be counterfeit, misbranded, or adulterated; and

''(B) consult with the United States Trade Representative and United States Patent and Trademark Office to evaluate the effect of importations permitted under this section on trade and patent rights under Federal law.

''(2) REPORT.—Not later than 5 years after the effective date of final regulations issued pursuant to this section, the Comptroller General of the United States shall prepare and submit to Congress a report containing the study described in paragraph (1).'';

(3) in subsection (k)(2)—

(A) by redesignating subparagraphs (A) through (E) as subparagraphs (B) through (F), respectively; and

(B) by inserting before subparagraph (B) (as so redesignated) the following subparagraph:

''(A) The term 'discrimination' includes a contract provision, a limitation on supply, or other measure which has the effect of providing United States pharmacists, wholesalers, or consumers access to covered products on terms or conditions that are less favorable than the terms or conditions provided to any foreign purchaser of such products.'';

(4) by striking subsection (m); and

(5) by inserting after subsection (l) the following subsection:

''(m) FUNDING.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for fiscal year 2002 and each subsequent fiscal year.''.

**SEC. 6. REASONABLE PRICE AGREEMENT FOR FEDERALLY FUNDED RESEARCH.**

(a) IN GENERAL.—If any Federal agency or any nonprofit entity undertakes federally funded health care re-

search and development and is to convey or provide a patent or other exclusive right to use such research and development for a drug or other health care technology, such agency or entity shall not make such conveyance or provide such patent or other right until the person who will receive such conveyance or patent or other right first agrees to a reasonable pricing agreement with the Secretary of Health and Human Services or the Secretary makes a determination that the public interest is served by a waiver of the reasonable pricing agreement provided in accordance with subsection (c).

(b) CONSIDERATION OF COMPETITIVE BIDDING.—In cases where the Federal Government conveys or licenses exclusive rights to federally funded research under subsection (a), consideration shall be given to mechanisms for determining reasonable prices which are based upon a competitive bidding process. When appropriate, the mechanisms should be considered where—

(1) qualified bidders compete on the basis of the lowest prices that will be charged to consumers;

(2) qualified bidders compete on the basis of the least sales revenues before prices are adjusted in accordance with a cost-based reasonable pricing formula;

(3) qualified bidders compete on the basis of the least period of time before prices are adjusted in accordance with a cost-based reasonable pricing formula;

(4) qualified bidders compete on the basis of the shortest period of exclusivity; or

(5) qualified bidders compete under other competitive bidding systems.

Such competitive bidding process may incorporate requirements for minimum levels of expenditures on research, marketing, maximum price, or other factors.

(c) WAIVER.—No waiver shall take effect under subsection (a) before the public is given notice of the proposed waiver and provided a reasonable opportunity to comment on the proposed waiver. A decision to grant a waiver shall set out the Secretary's finding that such a waiver is in the public interest.

**SEC. 7. GAO ONGOING STUDIES AND REPORTS ON PROGRAM; MISCELLANEOUS REPORTS.**

(a) ONGOING STUDY.—The Comptroller General of the United States shall conduct an ongoing study and analysis of the prescription medicine benefit program under part D of the medicare program under title XVIII of the Social Security Act (as added by section 3 of this Act), including an analysis of each of the following:

(1) The extent to which the administering entities have achieved volume-based discounts similar to the favored price paid by other large purchasers.

(2) Whether access to the benefits under such program are in fact available to all beneficiaries, with special attention given to access for beneficiaries living in rural and hard-to-serve areas.

(3) The success of such program in reducing medication error and adverse medicine reactions and improving quality of care, and whether it is probable that the program has resulted in savings through reduced hospitalizations and morbidity due to medication errors and adverse medicine reactions.

(4) Whether patient medical record confidentiality is being maintained and safe-guarded.

(5) Such other issues as the Comptroller General may consider.

(b) REPORTS.—The Comptroller General shall issue such reports on the results of the ongoing study described in subsection (a) as the Comptroller General shall deem appropriate and shall notify Congress on a timely basis of significant problems in the operation of the part D prescription medicine program and the need for legislative adjustments and improvements.

(c) MISCELLANEOUS STUDIES AND REPORTS.—

(1) STUDY ON METHODS TO ENCOURAGE ADDITIONAL RESEARCH ON BREAKTHROUGH PHARMACEUTICALS.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall seek the advice of the Secretary of the Treasury on possible tax and trade law changes to encourage increased original research on new pharmaceutical breakthrough products designed to address disease and illness.

(B) REPORT.—Not later than January 1, 2003, the Secretary shall submit to Congress a report on such study. The report shall include recommended methods to encourage the pharmaceutical industry to devote more resources to research and development of new covered products than it devotes to overhead expenses.

(2) STUDY ON PHARMACEUTICAL SALES PRACTICES AND IMPACT ON COSTS AND QUALITY OF CARE.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study on the methods used by the pharmaceutical industry to advertise and sell to consumers and educate and sell to providers.

(B) REPORT.—Not later than January 1, 2003, the Secretary shall submit to Congress a report on such study. The report shall include the estimated direct and indirect costs of the sales methods used, the quality of the information conveyed, and whether such sales efforts leads (or could lead) to inappropriate prescribing. Such report may include legislative and regulatory recommendations to encourage more appropriate education and prescribing practices.

(3) STUDY ON COST OF PHARMACEUTICAL RESEARCH.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study on the costs of, and needs for, the pharmaceutical research and the role that the taxpayer provides in encouraging such research.

(B) REPORT.—Not later than January 1, 2003, the Secretary shall submit to Congress a report on such study. The report shall include a description of the full-range of taxpayer-assisted programs impacting pharmaceutical research, including tax, trade, government research, and regulatory assistance. The report

may also include legislative and regulatory recommendations that are designed to ensure that the taxpayer's investment in pharmaceutical research results in the availability of pharmaceuticals at reasonable prices.

(4) REPORT ON PHARMACEUTICAL PRICES IN MAJOR FOREIGN NATIONS.—Not later than January 1, 2003, the Secretary of Health and Human Services shall submit to Congress a report on the retail price of major pharmaceutical products in various developed nations, compared to prices for the same or similar products in the United States. The report shall include a description of the principal reasons for any price differences that may exist.

**SEC. 8. MEDIGAP TRANSITION PROVISIONS.**

(a) IN GENERAL.—Notwithstanding any other provision of law, no new medicare supplemental policy that provides coverage of expenses for prescription drugs may be issued under section 1882 of the Social Security Act on or after January 1, 2003, to an individual unless it replaces a medicare supplemental policy that was issued to that individual and that provided some coverage of expenses for prescription drugs.

(b) ISSUANCE OF SUBSTITUTE POLICIES IF PRESCRIPTION DRUG COVERAGE IS OBTAINED THROUGH MEDICARE.—

(1) IN GENERAL.—The issuer of a medicare supplemental policy—

(A) may not deny or condition the issuance or effectiveness of a medicare supplemental policy that has a benefit package classified as ''A'', ''B'', ''C'', ''D'', ''E'', ''F'', or ''G'' (under the standards established under subsection (p)(2) of section 1882 of the Social Security Act, 42 U.S.C. 1395ss) and that is offered and is available for issuance to new enrollees by such issuer;

(B) may not discriminate in the pricing of such policy, because of health status, claims experience, receipt of health care, or medical condition; and

(C) may not impose an exclusion of benefits based on a preexisting condition under such policy,

in the case of an individual described in paragraph (2) who seeks to enroll under the policy not later than 63 days after the date of the termination of enrollment described in such paragraph and who sub-

mits evidence of the date of termination or disenrollment along with the application for such medicare supplemental policy.

(2) INDIVIDUAL COVERED.—An individual described in this paragraph is an individual who—

(A) enrolls in a prescription drug plan under part D of title XVIII of the Social Security Act; and

(B) at the time of such enrollment was enrolled and terminates enrollment in a medicare supplemental policy which has a benefit package classified as ''H'', ''I'', or ''J'' under the standards referred to in paragraph (1)(A) or terminates enrollment in a policy to which such standards do not apply but which provides benefits for prescription drugs.

(3) ENFORCEMENT.—The provisions of paragraph (1) shall be enforced as though they were included in section 1882(s) of the Social Security Act (42 U.S.C. 1395ss(s)).

(4) DEFINITIONS.—For purposes of this subsection, the term ''medicare supplemental policy'' has the meaning given such term in section 1882(g) of the Social Security Act (42 U.S.C. 1395ss(g)).

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